

EXHIBIT 2

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF ILLINOIS

IN RE DEPAKOTE:)
D.W.K., JR. and parents MARY and)
DANIEL KALETA,) Case No. 14-CV-847-NJR-SCW
Plaintiffs,)
vs.)
ABBOTT LABORATORIES, INC.,)
Defendant.)

MEMORANDUM AND ORDER

ROSENSTENGEL, District Judge:

Pending before the Court are three motions *in limine* filed by Plaintiffs.¹

Defendant does not oppose much of the evidence sought to be excluded, provided that the exclusion is mutual which, of course, it will be. The matters still in dispute are ruled on below.

Again, the Court expects the parties to resolve objections to exhibits and deposition testimony to the extent the issues are addressed by the Court's *in limine* rulings. As stated in its previous order (*see* Doc. 285), the Court will not rehash *in limine* rulings and will only consider specific objections to exhibits and testimony that are not covered by these rulings. Any such evidentiary questions that will arise during the first

¹These motions are directed specifically to Plaintiffs D.W.K., Jr. and his parents, Mary and Daniel Kaleta. With the impending trial date of March 2, 2015, the Court rules only on the D.W.K. motions at this time.

week of trial shall be identified and presented to the Court no later than **noon** on **Friday, February 27, 2015**. Again, the Court expects these objections to be minimal following the Court's ruling on the motions *in limine*.

As explained in previous orders of the Court, this litigation involves a mass tort action, currently consisting of eighty-five cases on the undersigned District Judge's docket, in which numerous plaintiffs allege that they sustained personal injuries from the use of Abbott's prescription drug Depakote.² This mass tort action was reassigned to the undersigned District Judge from the docket of Judge David Herndon on May 19, 2014 (*See* Doc. 288 in Lead Case 12-cv-52). On July 25, 2014, the Court selected the following three bellwether cases for trial: D.W.K., Jr. and parents Mary and Daniel Kaleta (12-cv-57); E.P. and C.P. and parents Roger and Mindy Pyszkowski (to be tried together) (12-cv-56); and J.F. and parent Michelle Leal (13-cv-34) (*See* Doc. 304 in Lead Case No. 12-cv-52). The Court explained that D.W.K., Jr. and parents Mary and Daniel Kaleta (12-cv-57) would be tried first. For case management and docket control purposes, the Court opened a new case number, 14-cv-847-NJR-SCW, for these three cases only (12-cv-57, 12-cv-56, 13-cv-34). The Court then set a dispositive motion and *Daubert* motion deadline of December 1, 2014 (*Id.*). As to D.W.K., Jr. and parents Mary and Daniel Kaleta (12-cv-0057), the Court set a Final Pretrial Conference for February 9, 2015, and a Jury Trial date of February 17, 2015, which has since been moved to March

²"Depakote" refers to Abbott's group of prescription drugs with the basic active ingredient valproic acid. Depakote is also sometimes referred to by the chemical names "valproic acid," "valproate," or "divalproex sodium." Depakote is an anti-epilepsy drug ("AED") that has been marketed by Abbott in the United States in some form since 1978.

2, 2015 (See Docs. 1 & 49 in Case No. 14-cv-847).

A district court's authority to rule on motions *in limine* is derived from its inherent authority to control the course of trials. *See Luce v. United States*, 469 U.S. 38, 41, n. 6 (1984). “[A] motion *in limine* should be granted only if the evidence sought to be excluded is clearly inadmissible for any purpose.” *Noble v. Sheahan*, 116 F. Supp. 2d 966, 969 (N.D. Ill. 2000). Motions *in limine* are intended “to avoid the delay and occasional prejudice caused by objections and offers of proof at trial.” *Wilson v. Williams*, 182 F.3d 562, 566 (7th Cir. 1999). Such motions permit the district court to eliminate evidence “that clearly ought not be presented to the jury,” because it is inadmissible for any purpose. *Jonasson v. Lutheran Child and Family Services*, 115 F.3d 436, 440 (7th Cir. 1997). “[T]he party moving to exclude evidence *in limine* has the burden of establishing that the evidence is not admissible for any purpose.” *Euroholdings Capital & Inv. Corp. v. Harris Trust & Sav. Bank*, 602 F. Supp. 2d 928, 934 (N.D. Ill. 2009).

Motion *in limine* rulings “are made before the district court has had a chance to hear all of the evidence or see the trial develop.” *Currie v. Cundiff*, No. 09-cv-866-MJR, 2012 WL 2254356, at *1 (S.D. Ill. June 15, 2012). As such, these rulings are preliminary and may be revisited based on the court’s exposure to the evidence at trial. *Id.*; *United States v. Connelly*, 874 F.2d 412, 416 (7th Cir. 1989).

Some evidentiary submissions cannot be evaluated accurately or sufficiently prior to trial. *Jonasson*, 115 F.3d at 440. “In these instances, it is necessary to defer ruling until during trial, when the trial judge can better estimate its impact on the jury.” *Id.* Further, the denial of a motion *in limine* does not preclude a party from objecting to any

evidence at trial or from requesting a limiting instruction. *Team Play, Inc. v. Boyer*, No. 03-C-7240, 2005 WL 3320746, at *1 (N.D. Ill. Dec. 5, 2005).

The motions have been thoroughly briefed (with detailed motions, lengthy responses, and contentious reply briefs),³ and the Court heard from the parties concerning particular questions on certain motions at the February 9 final pretrial conference. For the reasons set forth below, the Court rules as follows:

1. **Plaintiffs' motion *in limine* No. 1 -- To exclude evidence or argument regarding: (1) potential effects of Plaintiffs' claims, (2) procedural posture of Plaintiffs' claims or character of the parties, (3) evidence that the FDA regulations preclude Plaintiffs' claims, (4) facts that are irrelevant, unfairly prejudicial or calculated to mislead the jury (Doc. 126).**

Although the succinct title of this motion suggests that it seeks to exclude only four issues, the motion actually contains thirty-eight subparts, each seeking to exclude a category of evidence. As noted above, the majority of these items are not opposed by Abbott, and the following evidence and argument will be excluded by agreement:

- That a verdict for Plaintiffs will adversely impact pharmaceutical companies' incentive/ability to develop new medications (No. 1);
- That an award of damages in this case or any other Depakote case will adversely affect the ability of any member of the jury to purchase or have available medications in the future, or affect the cost thereof, or have any adverse effect on the medical or health products available to individuals or industries in the United States or worldwide (No. 2);
- That a verdict for Plaintiffs will or could take away a prescription choice from

³The parties have filed reply briefs to every motion *in limine* in this case, in spite of the admonition in Local Rule 7.1 that “[r]eply briefs are not favored and should be filed only in exceptional circumstances.” SDIL-LR 7.1 (g) (bold in original). Local Rule 7.1 further provides that “the party filing the reply brief shall state the exceptional circumstances.” *Id.* Plaintiffs fail to specifically state the exceptional circumstances that warrant the filing of reply briefs for each of their motions *in limine*. The Court has nonetheless considered each reply rather than engaging in lengthy oral argument on each motion.

doctors (No. 3);

- That this case or any other Depakote case may have a negative impact on the stock value of Abbott's or any other publicly-traded pharmaceutical manufacturer (No. 4);
- That a verdict for the Plaintiffs in this case or any other Depakote case will or could result in people losing their jobs or lead to lay-offs (No. 5);
- That this case or any other Depakote case may cause an increase in the cost of purchasing or maintaining insurance (No. 6);
- Referring to a purported "litigation crisis," "lawsuit crisis," "lawsuit abuse," "lawyer driven litigation," or similar terms and phrases (No. 7);
- That Abbott may have limited policy limits or cash, or the effect or results of such judgment upon the insurance rates, premiums, finances, or ability of Abbott to compete in the marketplace (No. 8);
- That if Abbott is made to pay a judgment that it may negatively affect the economy in Illinois or any other state (No. 9);
- That Plaintiffs' recovery in this case may be subject to prejudgment interest or judgment interest (No. 10);
- That Plaintiffs' recovery will be increased or enhanced by operation of law (No. 11);
- That an award of punitive damages in this case is unconstitutional, illegal, or not supported by the current state of the law (No. 12);⁴
- That the Court has expressed a particular view of the evidence in this case (No. 15);
- That reflects (a) the financial status or resources of Plaintiffs' attorneys or their law firms, or any of those attorneys' other businesses or cases; (b) the means of travel for any of the lawyers or witnesses involved in this case; and (c) hotel accommodations for any of the lawyers, staff, or witnesses participating in the trial (No. 16);⁵

⁴ This does not, of course, preclude Abbott from arguing that *the evidence* does not support punitive damages under Illinois law.

⁵ Abbott contends that use of counsel's private jet for Plaintiffs' witnesses may be relevant to issues of

- Referring to Plaintiffs' fee agreement and who is paying expenses or who is responsible for expenses in connection with this litigation (No. 17);⁶
- Reflecting any settlement negotiations offered or demanded by the parties to this lawsuit that have occurred or may occur prior to or during trial (No. 21);
- Reflecting that Plaintiffs received, may be entitled to receive, or will receive, benefits of any kind or character from any housing, Medicaid, state sponsored program, or private insurance; and that any insurance has been received by Plaintiffs; or that he/she has been entitled to receive or may become entitled to receive any insurance benefits for the injuries and damages in this case (No. 22);
- Regarding the reasons or appropriateness of Chicago-area residents filing and/or pursuing a lawsuit in the Southern District of Illinois (No. 31);
- Regarding Plaintiffs' decision to call or not to call a witness live at trial (No. 32);
- Regarding the negligence of Plaintiffs' mothers or other third parties, including that Plaintiffs' mothers' treating or prescribing physicians were negligent, or that their conduct violated any standard of care, or that they failed to give adequate informed consent as to Depakote, or that Plaintiffs did not sue other potential parties such as physicians (No. 34);⁷

The Court resolves the disputed issues as follows:

- That Abbott should not be subjected to tort laws of the 50 states and the District of Columbia (No. 13);

GRANTED in part. The jury will, of course, be instructed that this case is governed by the substantive law of the State of Illinois and federal law.

- That state law should be preempted by federal law (No. 14);

credibility and bias. That issue will be taken up at the appropriate time during trial.

⁶ Again, evidence relating to the compensation of Plaintiffs' experts may be relevant to issues of credibility and bias.

⁷ This does not preclude "factual testimony about what Plaintiffs' mother (specifically, Mrs. Kaleta, in this case), including her doctors, knew or did not know about the risks of Depakote, the actions and decisions they did or did not take regarding same, and the advice relating to the factual circumstances surrounding the use of Depakote prior to and during pregnancy." (See Doc. 218, p. 13).

GRANTED. The parties should not argue preemption issues to the jury. *See also* Court's ruling on Abbott's motion *in limine* No. 1 with respect to preempted labeling issues (Doc. 285).

- Referring to the timing of Plaintiffs' lawsuit being filed (No. 18);

GRANTED in part. Neither side should elicit testimony or argue that there is something inappropriate about the passage of time between D.W.K.'s birth and the trial and/or the natural unavailability of witnesses and/or documents (*see* Abbott's motion *in limine* No. 10).

- Referring to character evidence regarding Abbott (Nos. 19, 20, 23);

GRANTED in part. If Plaintiffs open the door by attacking the character of Abbott's employees, Abbott may seek to admit testimony on the same issues. Otherwise, the evidence is likely not relevant.

- Referencing contacts between Plaintiffs' attorneys and the treating physicians (No. 24);

DENIED. There is nothing inappropriate about Plaintiffs' attorneys meeting with the treating physicians, and Illinois Pattern Instruction ("IPI") No. 3.02 and/or 7th Circuit Civil Pattern Instruction No. 1.16 will so instruct the jury.

- That Abbott cannot be liable for Plaintiffs' injuries caused by Depakote because Abbott received FDA approval for Depakote (No. 25);

GRANTED in part/DENIED in part. The FDA standards and overall regulatory process are certainly relevant to the issues in this case. Abbott concedes it will not "argue to the jury that FDA approval of Depakote, in and of itself, is a complete defense to Plaintiffs' claims." (Doc. 218, p. 8). *See also* ruling on Abbott's motion *in limine* No. 1 (Doc. 285).

- That Abbott was prohibited from changing the Depakote label without prior approval from the FDA (No. 26);

GRANTED in part/DENIED in part. As it relates to D.W.K., the issue is whether Plaintiffs can argue that Abbott could have changed the label at issue via the Changes Being Effected ("CBE") process without prior approval from the FDA. As it relates to warning of developmental delay and changing the Black Box Warning, *see* ruling on Abbott's motion *in limine* No. 1 (Doc. 285). As to other evidence that Abbott could have

changed the Depakote label via the CBE process, Abbott will be allowed to explain that the FDA maintains the authority to accept, reject, or request modification of those changes.

- That state or federal product liability laws pressure drug manufacturers to add unsubstantiated, false, or invalid warnings in order to avoid lawsuits (No. 27) and that state tort law undercuts FDA's mission to provide only scientifically valid warnings or frustrates FDA's protective regime (No. 28);

GRANTED. Abbott concedes that it will not offer the evidence specifically addressed by the words of this motion *in limine*. Again, however, Abbott will be allowed to present evidence concerning the FDA regulatory process.

- About the date or circumstances under which Plaintiffs employed their attorneys, the name or any other lawyer retained or consulted by Plaintiffs (No. 29), and about how, when, or under what circumstances Plaintiffs chose or employed any attorneys (No. 30);

GRANTED. This evidence is not relevant to any issue in the case. Whether Mrs. Kaleta contacted her lawyers because of a television advertisement or a friend's recommendation has nothing to do with her claims or her credibility. *See In re Yasmin & Yaz (Drospirenone Mktg., Sales Practices & PMF Products Liab. Litig.*, No. 3:09-CV-10012-DRH, 2011 WL 6740391, at *16 (S.D. Ill. Dec. 22, 2011). Moreover, any probative value of this evidence (which is minimal, if existent at all), is substantially outweighed by the danger of unfair prejudice, confusing the issues, misleading the jury, undue delay, and wasting time.

- That Plaintiffs should not be able to recover damages for the future cost of care and supervision because family members or friends may be able to take care of the minor plaintiff (D.W.K.) (No. 33);

GRANTED. Illinois follows the "reasonable-value" approach to the collateral source rule and "allows all injured plaintiffs to recover the reasonable value of medical expenses and does not distinguish between those who have private insurance, those whose expenses are paid by the government, or those who receive their treatment *on a gratuitous basis*." *See Wills v. Foster*, 892 N.E.2d 1018, 1030 (Ill. 2008) (emphasis added). Moreover, gratuitous care is not guaranteed or even legally required after the minor plaintiff turns 18.

- That the relevant Depakote label was adequate because D.W.K.'s injuries "are

within the scope of the label" or "covered by the label" (No. 35);

DENIED. This evidence goes to the heart of Abbott's defense in the case (i.e., that the warning in the label was adequate).

- That D.W.K.'s injuries were caused by genetics, have a genetic origin, or are of a genetic etiology, rather than by ingestion of Depakote (No. 36), and that D.W.K.'s mother could have prevented his congenital malformations by taking folic acid during her pregnancy (No. 37);

DENIED. This evidence is relevant to the issue of causation.

- That there was no risk of pregnancy for Mrs. Kaleta or that she should not have expected to become pregnant because of the use of some form of birth control (No. 38);

DENIED. The parties conceded at the final pretrial conference (*see* Doc. 279, p. 75) that this will not be an issue in the D.W.K. case because Mrs. Kaleta will testify that she wanted to get pregnant.

2. To preclude Abbott from offering evidence relating to Plaintiffs' contention interrogatories (Doc. 129).

DENIED. Plaintiffs never brought the objections to these interrogatories to Magistrate Judge Williams despite numerous, frequent opportunities to do so. Additionally, the Court fails to find prejudice from the late verifications, because the substantive responses to these interrogatories did not change.

3. To exclude evidence of (1) the minor Plaintiff's mother being [REDACTED] (3)

[REDACTED] (4) any evidence that something other than Plaintiff's mother's ingestion of Depakote contributed to Plaintiff's injuries, (5) any evidence that Plaintiffs' mother [REDACTED]

[REDACTED] (Docs. 137, 138).⁸

GRANTED in part/DENIED in part. The first portion of this motion *in limine* relates to the other bellwether cases and not Mrs. Kaleta. Abbott has agreed not to mention [REDACTED] unless Plaintiffs open the door.

⁸ This motion is the fifth motion *in limine* filed by Plaintiffs, but the third and fourth address the other bellwether Plaintiffs, so the Court will not consider them at this time. And, as discussed, only portions of this motion *in limine* relate to D.W.K.

Abbott also agrees that evidence relating to [REDACTED]

[REDACTED] is not admissible. As discussed above, because Abbott disputes causation, evidence "that something other than Plaintiff's mother's ingestion of Depakote contributed to D.W.K.'s injuries" will be allowed. Finally, Abbott has indicated that it does not intend to make affirmative use of [REDACTED]

[REDACTED] which may be relevant evidence on the issue of causation.

IT IS SO ORDERED.

DATE: February 20, 2015

s/ Nancy J. Rosenstengel
NANCY J. ROSENSTENGEL
United States District Judge